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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,121	05/16/2003	Karin Klokke	4271-34PUS	8059

7590 04/01/2008  
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EXAMINER
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GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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04/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/019,121	<b>Applicant(s)</b> KLOKKERS ET AL.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-7 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 10-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment and declaration, both filed 06/25/2007; and request for RCE filed 12/26/2007.

Claims 2, 8 and 9 have been canceled. Claims 20 and 21 have been added.

Claims 1, 3-7 and 10-21 are pending and are included in the prosecution.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/26/2007 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1, 3-7, 10-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is in improper Markush format. Proper Markush format to be followed in the claim should have the expression "selected from the group consisting of", and only the last two members of the Markush group are separated by the connector operator "and" OR "or". Claims 1 and 3 read as the last member of the Markush is "trandolapril", and only "trandolapril" in the form of dicarboxylic acid.

Claim 3 is in improper dependent form for failing to further limit the subject matter of a previous claim 1 from which it depends.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-7 and 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 6,303,141 ('141) and EP 349 430 ('430).

US '141 teaches transdermal drug delivery device comprising backing layer, matrix containing 10% ACE inhibitor and Eutanol G as permeation enhancer, and protective release liner. The ACE inhibitor is at least one of ramipril ortrandolapril in the acid form or active salt which reads on monosalts. The ACE inhibitor is present in the form of prodrug or active form, i.e. dicarboxylic acid, salts and esters (abstract; col.2, lines 25-30, 37-43; the claims).

Although US '141 teaches active salts and acid of ACE inhibitors, it does not specifically teach monosalts as claimed by claim 1. US '141 does not teach the cover over the backing layer that is larger than the backing as claimed by claims 14-17.

The cover sheet and its size do not impart patentability to the claims, absent evidence to the contrary.

EP '430 teaches a transdermal system that has improved flux through the skin achieved by using specific salt forms of the drug (page 2, lines 45-50). The transdermal system has a top layer, a layer containing ACE inhibitor, an adhesive layer and protective layer (page 3, lines 40-50). The reference also disclosed on page 3 lines 4-10 the salt forms of the drugs including methane sulphonate and dicarboxylate such as

maleate. Example 1 shows that ACE inhibitors are present as monosalts such as libenzapril monomaleate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal system for delivery of salts of ACE inhibitors as disclosed by US '141, and replace the salt of ACE inhibitor by monosalts as disclosed by EP '430, motivated by the teaching of EP '430 that transdermal system that having monosalts ACE inhibitors showed improved flux through the skin, with reasonable expectation of having transdermal system for delivery of monosalts of ACE inhibitors at improved flux rates.

### ***Response to Arguments***

7. Applicant's arguments filed 12/27/2007 have been fully considered but they are not persuasive. The main gist of applicants' argument is that US '141 and EP '430 do not teach monosalts of the specific claimed compounds.

In response to above argument, it is argued the present claims are directed to product, and all the elements of the product are disclosed by the combined teaching of the prior art. US '141 teaches esterified dicarboxylic acid ACE inhibitors. On col.2, lines 26-28, US '141 teaches the use of ramipril ortrandolapril in their active acid form or active salt forms. Instant claim 20 encompasses wide range of salts. With regard to EP '430, the examiner is pointing to page 3 lines 4-10 of EP '430 wherein the salt forms of the drugs including methane sulphonate and dicarboxylate such as maleate. Further,

the examiner is pointing to page 3 lines 4-10 of EP '430 wherein the salt forms of the drugs including methane sulphonate and dicarboxylate such as maleate.

Therefore, the art recognized monosalts of ACE inhibitors in general and only exemplified some of the drugs. The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicants further argue that the present composition is more stable than the prior art.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., product stability) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

***Response to Amendment***

8. The declaration under 37 CFR 1.132 filed 06/25/2007 is insufficient to overcome the rejection of claims 1, 3-7, 10-21 based upon combination of US '141 and EP '430 as set forth in the last Office action because: the two compared compositions are not equivalent in terms of composition. The two compositions having two different purity values at the start and two different adhesive compositions. The adhesive may have detrimental effect on stability of the drugs. Additionally, the permeation of the second composition was not tested to show any change such diminished permeability after storage. Therefore, the declaration presents improper comparison between the present product and the other products. Proper and meaningful comparison can only be made by comparing two different drugs while other parameters are the same such as the adhesive, purity, etc. Absent such proper comparison, the prior art/comparative product is not any different from the instant product.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

***Minor Informalities***

9. Claim 14 contain typographical error in 5<sup>th</sup> line of the claim, which is the phrase "but not does not".



10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/  
Primary Examiner, Art Unit 1611